

DISTRICT OF NEVADA

BARBARA HEINRICH and GREGORY
HEINRICH,

Plaintiffs

V.

ETHICON, INC.; ETHICON LLC; and
JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

**Order Granting in Part the Defendants’
Motion to Exclude Opinions of Bruce
Rosenzweig**

[ECF No. 102]

This case was part of multidistrict litigation (MDL) assigned to the United States District Court for the Southern District of West Virginia concerning the use of transvaginal surgical mesh to treat stress urinary incontinence (SUI). Plaintiff Barbara Heinrich alleges that she suffered injuries after having the TVT-SECUR (TVT-S) product implanted. The TVT-S was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc. ECF No. 4 at 3.

The defendants move to preclude Dr. Bruce Rosenzweig from: (1) testifying that non-synthetic mesh procedures, such as autologous or allograft slings, or Burch colposuspensions, are safer alternatives to TVT-S; (2) opining that mechanical cut mesh is a safer alternative to laser cut mesh; and (3) testifying about duties a medical device manufacturer owes regarding adverse event collection and physician training.

The parties are familiar with the facts, so I recount them here only as necessary to resolve the motion. I grant the motion in part.

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1 **I. ANALYSIS**

2 Federal Rule of Evidence 702 governs the admissibility of Dr. Rosenzweig’s opinions.
3 Under Rule 702, a witness “who is qualified as an expert by knowledge, skill, experience,
4 training, or education may testify in the form of an opinion or otherwise if”:

- 5 (a) the expert’s scientific, technical, or other specialized knowledge will
6 help the trier of fact to understand the evidence or to determine a fact in
7 issue;
8 (b) the testimony is based on sufficient facts or data;
9 (c) the testimony is the product of reliable principles and methods; and
10 (d) the expert has reliably applied the principles and methods to the facts
11 of the case.

12 To be admissible, expert testimony thus must be both relevant and reliable. “Expert opinion
13 testimony is relevant if the knowledge underlying it has a valid connection to the pertinent
14 inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge
15 and experience of the relevant discipline.” *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)
16 (quotation omitted), *as amended* (Apr. 27, 2010). Medical expert testimony should be admitted
17 “if physicians would accept it as useful and reliable, but it need not be conclusive because
18 medical knowledge is often uncertain.” *Id.* (quotation omitted). Where there is a sufficient
19 foundation for the testimony, it is up to the jury to evaluate the expert’s credibility. *Id.* at 565-66.

20 The proponent of expert testimony “has the burden to establish its admissibility.” *United*
21 *States v. 87.98 Acres of Land More or Less in the Cnty. of Merced*, 530 F.3d 899, 904 (9th Cir.
22 2008). But Rule 702’s inquiry is “flexible,” and should be applied in favor of admitting the
23 evidence. *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017) (quotation
omitted). “Shaky but admissible evidence is to be attacked by cross examination, contrary
evidence, and attention to the burden of proof, not exclusion.” *Primiano*, 598 F.3d at 564.

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1 **A. Alternative Procedures**

2 The defendants argue that Dr. Rosenzweig should not be allowed to opine that autologous
3 or allograft slings, or Burch colposuspensions are safer alternative procedures for the treatment
4 of SUI because these are alternative surgical procedures, not alternative safer designs of the
5 defendants' medical device, so his testimony on this point is irrelevant. The defendants assert
6 that identifying safer alternative procedures takes issue with Heinrich's implanting surgeon's
7 decision to recommend the TVT-S over these other procedures, but does not reflect whether
8 there is a safer alternative design for the TVT-S.

9 Heinrich responds that Dr. Rosenzweig's opinions are relevant to whether the TVT-S was
10 unreasonably dangerous because the comparison with alternative procedures may show that the
11 TVT-S was more dangerous than the ordinary user would contemplate given other efficacious
12 options with fewer complications. Heinrich also contends that Dr. Rosenzweig's opinions are
13 relevant to her negligence claim to "explain to the jury that women with [SUI] are not restricted
14 to mesh devices and that synthetic slings are not the most successful procedures for SUI." ECF
15 No. 106 at 5. She also asserts that the opinions are relevant to her request for punitive damages
16 because "[m]any doctors who used non-mesh procedures later used synthetic mesh devices after
17 manufacturers were willing to pay the doctors for 'teaching' the use of their products." *Id.*
18 Finally, Heinrich contends that the evidence is relevant to rebut Ethicon's assertions that the
19 TVT-S was the safest and most effective treatment for SUI.

20 To establish a strict products liability claim under Nevada law, a plaintiff must show:
21 "1) the product had a defect which rendered it unreasonably dangerous, 2) the defect existed at
22 the time the product left the manufacturer, and 3) the defect caused the plaintiff's injury."
23 *Fyssakis v. Knight Equip. Corp.*, 826 P.2d 570, 571 (Nev. 1992). A product is unreasonably

1 dangerous if it fails to perform “in the manner reasonably to be expected in light of [its] nature
2 and intended function” and “was more dangerous [than] would be contemplated by the ordinary
3 user having the ordinary knowledge available in the community.” *Allison v. Merck & Co., Inc.*,
4 878 P.2d 948, 952 (Nev. 1994) (quotation omitted). Evidence that the product in question
5 “lacked adequate safety features or that a safer alternative design was feasible at the time of
6 manufacture will support a strict liabilities claim.” *Fyssakis*, 826 P.2d at 572. However, proving
7 that an alternative safer design existed is not required for the plaintiff to prove her case. *Ford*
8 *Motor Co. v. Trejo*, 402 P.3d 649, 655-57 (Nev. 2017) (en banc).

9 Heinrich does not argue that Dr. Rosenzweig should be allowed to testify that the Burch
10 procedure or autologous or allograft slings are feasible alternative designs for the TVT-S
11 product. She thus does not appear to contest Judge Goodwin’s analysis in *Mullins v. Johnson &*
12 *Johnson*:

13 Evidence that a surgical procedure should have been used in place of a device is
14 not an alternative, feasible design in relation to the TVT. Whether an alternative
15 procedure could have been performed without the use of the TVT does nothing to
16 inform the jury on the issue of an alternative, feasible design for the TVT.

17 Instead, alternative surgeries or procedures raise issues wholly within the context
18 of what a treating physician has recommended for patients based on the individual
19 needs and risk factors associated with individual patients. In other words,
20 alternative surgeries or procedures concern the medical judgment of the doctors
21 who use TVT devices to treat stress urinary incontinence (“SUI”); other surgeries
22 or procedures do not inform the jury on how the TVT’s design could have
23 feasibly been made safer to eliminate the risks that caused the plaintiff’s injuries.

236 F. Supp. 3d 940, 943 (S.D. W. Va. 2017) (emphasis omitted). Because Heinrich bears the
burden of showing Dr. Rosenzweig’s testimony is admissible, and she does not argue that it is
admissible for the purpose of showing alternative feasible designs, Dr. Rosenzweig’s testimony
about the alternative procedures is inadmissible to show alternative feasible safer designs of
mesh devices existed.

1 Dr. Rosenzweig's testimony about other procedures also is not relevant to whether the
2 TVT-S is unreasonably dangerous or whether the defendants were negligent because it takes
3 issue with the choice of treatment recommended by Heinrich's implanting physician, Dr. Hsieh.
4 Even if there was some relevance to this evidence, the probative value is substantially
5 outweighed by the danger of unfair prejudice, confusion, and waste of time. Fed. R. Evid. 403.
6 This evidence would result in exploration of whether Dr. Hsieh made the proper medical choice
7 among available alternatives for Heinrich's particular circumstances, instead of whether the
8 defendants' product is unreasonably dangerous for its intended use or the defendants were
9 negligent. *Mullins*, 236 F. Supp. 3d at 943.

10 Heinrich does not explain how the alternative procedures are relevant to punitive
11 damages. To the extent the defendants paid doctors to use their product over other options, that
12 does not make admissible Dr. Rosenzweig's opinion that these other procedures are safer
13 alternatives.

14 However, Dr. Rosenzweig's opinions may be relevant to rebut the defendants' evidence
15 at trial. Heinrich notes that the defendants and their experts often tout TVT-S as the "gold
16 standard" for treating SUI while it was on the market. Evidence that other available procedures
17 were just as efficacious without the attendant alleged complications is relevant to rebut that
18 testimony. Consequently, Dr. Rosenzweig's testimony may be admissible if the defendants open
19 the door at trial. I therefore grant in part and deny in part this portion of the defendants' motion.

20 **B. Mechanical Versus Laser Cut Mesh**

21 The defendants argue that Dr. Rosenzweig should not be able to opine that mechanical
22 cut mesh is a safer alternative to the laser cut mesh in the TVT-S because he has opined that both
23 laser and mechanical cut mesh are unsafe. According to defendants, when Dr. Rosenzweig

1 testifies in a case involving laser cut mesh, he opines that the mesh is too stiff and that makes it
2 more dangerous than mechanical cut mesh. But when he testifies in a case involving
3 mechanically cut mesh, he opines that the mesh can rope, curl, and fray, and that makes it more
4 dangerous than laser cut mesh. Additionally, the defendants argue that mechanically cut mesh
5 was not an available option for the TVT-S, no expert has opined that Heinrich was injured by the
6 way the mesh was cut, and Dr. Rosenzweig cites no studies in support of his conclusion.

7 Heinrich responds that the issue under Nevada law is not whether mechanically cut mesh
8 would be safer, but whether laser cut mesh is unreasonably dangerous. She contends that Dr.
9 Rosenzweig opines that laser cut is unreasonably dangerous because it is too stiff and rigid, and
10 her other expert, Dr. Kim, opines that the stiffness and rigidity caused Heinrich's injuries. As to
11 Dr. Rosenzweig's inconsistent positions, Heinrich argues that is a matter for cross examination,
12 not exclusion.

13 In his TVT-S report, Dr. Rosenzweig opines that laser cut mesh is stiffer than
14 mechanically cut mesh. ECF No. 102-1 at 14. He states that laser cut mesh "can cause a
15 statistically higher incidence of erosion and sexual dysfunction than mechanically cut mesh." *Id.*
16 at 15. Finally, he opines that laser cut mesh "is defective because it is too stiff and rigid. As a
17 result, the mesh increases complications including chronic pain, chronic dyspareunia, erosions,
18 and urinary dysfunction." *Id.*

19 In his report on TVT products generally, he concludes that mechanically cut mesh is
20 defective because it is subject to particle loss, fraying, roping, curling, deformation, and loss of
21 pore size that leads to various complications. ECF No. 102-4 at 38-50. At his deposition in
22 another case, Dr. Rosenzweig confirmed that he finds SUI slings defective when they are both
23 laser cut and mechanically cut. ECF No. 102-7 at 3. And in another case, he testified that laser

1 and mechanically cut mesh lead to the same complications, albeit by “different mechanisms.”
2 ECF No. 102-8 at 3.

3 Any inconsistencies in Dr. Rosenzweig’s opinions about whether laser versus
4 mechanically cut mesh are safer alternative designs to each other are matters for cross
5 examination, not exclusion. *See Ellerbee v. Ethicon, Inc.*, No. 8:20-CV-1514-TPB-AEP, 2021
6 WL 2010640, at *3 (M.D. Fla. May 20, 2021); *Laderbush v. Ethicon, Inc.*, No. 20-CV-62-JD,
7 2020 WL 3001958, at *2 (D.N.H. June 4, 2020). And the evidence is relevant in this case. Dr.
8 Rosenzweig opines that laser cut mesh is stiffer than mechanically cut mesh, and Dr. Kim opines
9 that the mesh’s stiffness and rigidity contributed to Heinrich’s injuries. ECF Nos. 102-1 at 4, 14-
10 15; 102-6 at 15-16. I therefore deny this portion of the defendants’ motion.

11 **C. Manufacturer Duties**

12 1. Adverse Events

13 In their motion, the defendants argue that Dr. Rosenzweig should not be allowed to
14 testify that Ethicon’s collection and report of adverse events and complications was incomplete,
15 inaccurate, and misleading. In their reply, they narrow their request to exclude only his opinion
16 that Ethicon’s collection of adverse events and complications was incomplete, inaccurate, or
17 misleading.¹ ECF No. 113 at 109-10. The defendants contend that Dr. Rozenzweig has no
18 experience in the medical device industry that would make him qualified to opine on the
19 standard of care for a medical device manufacturer to collect adverse event information. They
20 also assert his opinion is merely a recitation of corporate documents.

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23 ¹ Dr. Rosenzweig therefore is not precluded from opining about whether Ethicon adequately
reported (as opposed to collected) adverse events and complications.

1 Heinrich responds that Dr. Rosenzweig's opinion goes to Ethicon's failure to warn
2 physicians and patients of adverse events. She also contends it is relevant to whether Ethicon
3 acted with conscious disregard to patient safety because it failed to collect and report adverse
4 events and complications to physicians and patients.

5 Dr. Rosenzweig opines that "Ethicon's collection and reporting of adverse events and
6 complications to physicians and patients is misleading, inaccurate and incomplete." ECF No.
7 102-1 at 5. He critiques Ethicon's "passive system of measuring how many and what type of
8 adverse events the TVT-S was causing." *Id.* at 66-67. And he contends that internal documents
9 show Ethicon was actively avoiding collecting complaints from physicians and had flawed
10 systems for collecting complaints. *Id.* at 67-70.

11 Heinrich cites to various pages of Dr. Rosenzweig's depositions, but she does not identify
12 what in his experience or education qualifies him to opine on the quality of a medical device
13 manufacturer's system for collecting adverse event reports. She therefore has not met her burden
14 of showing Dr. Rosenzweig's testimony on adverse report collection is admissible. And, as the
15 MDL court has ruled, she may not use an expert "solely [as] a conduit for corporate
16 information." ECF No. at 20-21. Consequently, I grant this portion of the defendants' motion as
17 narrowed in its reply brief.

18 2. Physician Training

19 The defendants argue Dr. Rosenzweig should be precluded from opining that Ethicon did
20 not properly train physicians on how to use the TVT-S because he is not qualified to opine on
21 what training a medical device manufacturer should provide. Additionally, the defendants argue
22 this evidence is irrelevant because no one has opined that Heinrich's implanting physician, Dr.
23 Hsieh, improperly implanted the device.

1 Heinrich responds that Dr. Rosenzweig is qualified to render those opinions because he
2 testified to his qualifications and the basis of his conclusion that Ethicon provided inadequate
3 training, and because he has trained other physicians in surgical techniques. She also argues that
4 the MDL court has already ruled that Dr. Rosenzweig is qualified to testify about the sufficiency
5 of the warnings and training materials for the TVT-O, and those same qualifications would apply
6 to the TVT-S. She contends that Dr. Rosenzweig is qualified to testify about the training
7 actually provided and whether it was adequate. As for Dr. Hsieh, she argues that Ethicon
8 undertook the duty to train him, and its failure to do so increased the risk of harm to Heinrich.²

9 Dr. Rosenzweig may not opine that Dr. Hsieh was inadequately trained because Heinrich
10 has not shown that anyone will opine that Dr. Hsieh was inadequately trained or that he
11 improperly implanted the TVT-S. Consequently, whether the defendants failed to train Dr.
12 Hsieh is irrelevant to the issues in this case because there is no evidence that any failure to train
13 led to Heinrich's injuries.

14 Additionally, Dr. Rosenzweig may not opine that despite being aware of problems
15 associated with the implantation of the TVT-S, "Ethicon failed to offer adequate
16 training/retraining to physicians." ECF No. at 79. Heinrich does not point to anything in Dr.
17 Rosenzweig's experience or education that would qualify him to opine on what duty (if any) a
18 manufacturer has to train physicians on the proper use of its product. And, as discussed above,
19 she may not use an expert "solely [as] a conduit for corporate information." ECF No. at 20-21.
20 Consequently, I grant this portion of the defendants' motion.

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23 ² Heinrich asserts that this evidence may be admissible on rebuttal. The defendants do not respond to that argument. I reserve that issue for trial should it arise.

1 **II. CONCLUSION**

2 I THEREFORE ORDER that the defendants' motion to exclude certain opinions of Dr.
3 Bruce Rosenzweig (**ECF No. 102**) is **GRANTED in part**.

4 DATED this 4th day of June, 2021.

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7 ANDREW P. GORDON
8 UNITED STATES DISTRICT JUDGE
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